



MODEL CONSENT FORM FOR SUPPLEMENTAL NEWBORN SCREENING

General Information about Newborn Screening in Nebraska

Nebraska law says that every newborn **MUST** be tested for certain disorders (described in the state's newborn screening brochure) that could lead to serious problems if they are not found and treated right away. The Nebraska Department of Health and Human Services manages this program. We will be testing your baby for these conditions, using blood from your baby's heel. We prick the heel and squeeze a few drops of blood onto a piece of paper. There is a tiny chance of prolonged bleeding if your baby's blood does not clot normally or if your baby is on a blood thinner. Your baby may get a small bruise. There is a small chance of infection.

As with all laboratory tests, there is a slight chance for error. Sometimes samples are damaged in transport. Sometimes samples are labeled wrong, the equipment doesn't run correctly or the results are not interpreted correctly. The chance this will happen, and escape detection, is small because safeguards are built in.

The sample will be sent to a special laboratory. No one else will have access to it. The laboratory will keep the sample for 3 months in case the test needs to be repeated, then it will destroy the sample. Test results will be kept by the laboratory; the hospital or clinic where your baby's blood was drawn; your doctor's office; and the State Department of Health and Human Services. Sometimes parents may be asked to donate their baby's sample for research after testing is complete. If that happens, a separate permission form will be used for the donation.

This is a first-step, screening test. Your doctor will call you if more testing is needed to see if your baby really has one of these conditions.

You or your insurance company will be billed for the tests.

Your baby's sample will be sent to the lab contracting with the State Department of Health and Human Services to perform the screening: _____

(Name of Laboratory)

NEBRASKA REQUIRED NEWBORN SCREENING

The conditions for which screening is required are:

PKU (phenylketonuria) -- requires special diet

galactosemia -- requires special diet

biotinidase deficiency -- requires daily vitamin supplement

congenital primary hypothyroidism -- requires daily medicine

hemoglobin variations -- may require medicine and other care

MCAD -- requires special attention during illness

*Congenital adrenal hyperplasia * -- requires daily medicine*

Cystic fibrosis -- requires daily medicine & special diet*

** (for specimens received at the newborn screening laboratory on or after January 2, 2006)*

SUPPLEMENTAL NEWBORN SCREENING

When we send your baby's blood sample to be tested for MCAD and PKU, the sample goes through a machine that can test many different things in your baby's blood. These results can show other disorders which are **NOT** on the state's required testing list. The supplemental screening results will only be done if you give permission. If you decide against supplemental screening and later change your mind, a new blood sample will be needed, and new fees will be charged.

The types of disorders found by the supplemental screening are described at the end of this form. These disorders are rare, and they can be hard for your baby's doctor to diagnose. This screening test does not show all possible disorders, but it covers about 30 conditions. Their names are listed in the state newborn screening brochure.

Here are some reasons people might want to know the additional information:

some disorders can cause poor growth

*some disorders can cause sudden, very serious illness, permanent disability, or death without screening, it can be slow and expensive to figure out what's wrong
many disorders can be treated, making the illness less severe or less frequent
the information could be important to other family members*

baby's name _____
date of birth _____
ID number _____

Here are some reasons people might not want to know the additional information:

*some treatments are not proven
some disorders may cause death or disability despite medical help
some disorders cause problems for only a few people who have them
sometimes we can't tell whether a pattern is normal or abnormal
final testing may show that the screening result was a false alarm
rarely, the screening test will be normal when the child actually has a disorder
some people worry about possible discrimination in employment or insurance*

This is a first-step, screening test. Your doctor will call you if more testing is needed to see if your baby really has one of these disorders. The screening results should be back in 5-10 days.

You will receive a copy of this form. If you have questions later, call this person: _____ at this number: _____.

Accept Supplemental Screening Results

After reviewing this information, I have decided to receive the supplemental screening test.

parent, guardian or representative

date

physician or physician's delegate

Decline Supplemental Screening Results

After reviewing this information, I have decided NOT to receive the supplemental screening test.

parent, guardian or representative

date

physician or physician's delegate

Description of disorders in the Supplemental Screening Test Panel

The supplemental screen includes the following types of disorders. The names of the conditions are listed in the state newborn screening brochure.

Fatty acid disorders. People with these disorders cannot turn fat into energy in the normal way. They may get low blood sugar, muscle weakness, very low energy, seizures, coma, liver damage, permanent mental or physical disability, or death. Problems may appear in infancy, childhood, adulthood, only during illness, or never.

Amino acid disorders. People with these disorders cannot use certain proteins in the normal way. They may have mental retardation, developmental disabilities, seizures, blindness, or early death.

Organic acid disorders. People with these disorders have trouble using proteins and fats in the normal way. They may get any of the symptoms listed in "fatty acid disorders" and "amino acid disorders."